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a frustoconical portion having a taper, the frustoconical portion associated with the exit end;

a nosepiece extending from end to end of the frustoconical portion, and wherein the frustoconical portion opens radially into the nosepiece;

a one-way valve near the exit end of the aerosolization chamber and located in an opening in the mask, the one-way valve preventing backflow into the aerosolization chamber; and

a vertical valve formed in the upstream end of the frustoconical portion, the vertical valve operative to prevent air flow through the opening upon patient inhalation but which permits air flow through the opening upon exhalation into the mask so as to permit a patient wearing the mask to exhale air through the opening.

## IN THE SPECIFICATION

On page 1, immediately after the title please add -- This is a continuation of U.S. Serial Number 08/842,956, filed April 25, 1997, claiming priority of U.S. Serial No. 08/270,752, filed on July 5, 1994, which applications are hereby incorporated by reference. -- *N.E.*

## REMARKS

The specification and claims of this continuation application of U.S. Serial Number 08/842,956, filed April 25, 1997, claiming priority of U.S. Serial No. 08/270,752, filed on July 5, 1994 are amended by this Preliminary Amendment. This continuation application is being filed during the co-pendency of U.S. Serial Number 08/842,956 filed April 25, 1997, which has received a Notice of Allowability dated August 10, 1999.

In U.S. Serial No. 08/842,956, the Examiner indicated that claims 16-27, 30 and 31 are allowable. As such, these claims have been cancelled from the present continuation application. Applicant requests that remaining claims 15, 28-29, and 32-42, which were cancelled in the parent application, U.S. Serial No. 08/842,956, be acted upon in the present continuation application.

Claim 34 has been amended in this application. In the Office Action of January 4, 1999 in U.S. Serial No. 08/842,956, the Examiner rejected “[c]laims 16, 17, 22-27, 30, 34, 36, and 38 under 35 U.S.C. § 102(b) as being clearly anticipated by Schaefer.” Claims 16, 17, 22-27, and 30 have been canceled in this application and therefore their rejection has been rendered moot in this continuing application. Independent claim 34 has been amended to include the limitations of claim 39 of U.S. Serial No. 08/842,956. The Examiner did not reject claim 39 under 35 U.S.C. § 102(b) in the parent application. As this element is novel over the cited reference and has been incorporated into amended claim 34, amended independent claim 34, and any claims dependent therefrom, is also novel. Therefore, applicant respectfully asserts that the Examiner’s rejection of claim 34 has been successfully overcome and requests further action commensurate thereon.

In the Office Action of January 4, 1999 in U.S. Serial No. 08/842,956, the Examiner rejected claim 39 under 35 U.S.C. § 103(a) as being unpatentable over Schaefer in view of Katz et al and Booharin. Applicant submits that the subject matter of these claims is not obvious over this combination of references because the Examiner has provided no motivation for making this combination, as required by MPEP 2142-2144. These sections of the MPEP specifically establish the requirement that there must be a suggestion or motivation to modify the cited references to support a rejection for obviousness. As stated in the MPEP:

“[o]bviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art.” (MPEP 2143.01, quoting from *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q. 2d 1596 (Fed. Cir. 1988).

Further, MPEP 2143.01, citing *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990) :

“[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.” (emphasis in the original).

These MPEP sections are in accord with numerous well-established precedents. *In re Geiger*, 815 F. 2d 686, 2 U.S. P. Q. 2d 1271 (Fed. Cir. 1987); *N.V. Akzo v. E.I. du Pont de Nemours*, 810 F.2d 1148, 1 U.S. P.Q. 2d 1704 (Fed. Cir 1987); *In re Farrell*, 853 F.2d 894, 7 U.S.P.Q. 2d 1673 (Fed. Cir. 1988).

Furthermore, the Applicant respectfully asserts that the combination of Booharin and Katz et al in view of Schaefer is improper. The Examiner states that Schaefer fails to disclose the exhalation valve of the present invention. Booharin and Katz et al are directed to gas masks constructed so as to eliminate fogging of the eye lenses of the masks. One skilled in the art of exhalation valves for delivery of an aerosolized medicament would not refer or look to a non-analogous art directed to improvements in gas masks. *See* MPEP 21-41.01(a); *In re Oetiker*, 977 F.2d 1443, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992). Consequently, the combination of Booharin and Katz et al. in view of Schaefer is misapplied. Therefore, the Applicant respectfully asserts that claim 39 is unobvious over Booharin and Katz et al. in view of Schaefer.

Additionally, in the present case, the Examiner combined Katz et al. and Booharin with Schaefer. Arguably at best, Schaefer discloses an aerosolization chamber as claimed in the present invention. Further, one skilled in the art would not look to Booharin and Katz et al. to teach or suggest an exhalation valve for use in conjunction with an aerosolization chamber as claimed in claim 34. Further, there is no teaching or suggestion, either implicitly or explicitly, to combine these references. Therefore, Applicant respectfully submits that claim 34 is not rendered obvious.

Applicant incorporates herein the remarks of the Response of April 5, 1999 in U.S. Serial No. 08/842,956.

## **CONCLUSION**

In view of the amendments and remarks above, Applicant respectfully submits that all of the pending claims are in condition for allowance and seeks an early allowance thereof. If for any reason the Examiner is unable to allow the application in the next Office Action and believes that an interview would be helpful

to resolve any remaining issues, the Examiner is respectfully requested to contact the undersigned attorneys at (312) 321-4217.

Respectfully submitted,

  
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Vita G. Conforti  
Registration No. 39,639  
Attorney for Applicants

BRINKS HOFER GILSON & LIONE  
P.O. Box 10395  
Chicago, Illinois 60610  
(312) 321-4200